510(k) Summary

NEOORTHO PRODUTOS ORTOPÉDICOS S/A

DEC 20 2010

MINI AND MICRO FRAGMENTS RECONSTRUCTION SYSTEM - NEOFACE

October 19, 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name:	NEOORTHO Produtos Ortopédicos S/A Rua Ângelo Domingos Durigan, 607, Cascatinha Curitiba - PR 82020-340, Brazil Telephone: +55 41 3535-1033 Fax: +55 41 3535-1018
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Mini and Micro Fragments Reconstruction System – NEOFACE
Common Name:	Bone plate, Intraosseous bone screw
Classification Regulations:	21 CFR 872.4760, 21 CFR 872.4880
	Class II
Product Code:	JEY, DZL
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

Mini and Micro Fragments Reconstruction System – NEOFACE is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.

DEVICE DESCRIPTION

Mini and Micro Fragments Reconstruction System – NEOFACE is a fixation system for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin. It consists of implant plates and implant screws. The plates of the subject system include mini and micro fragment reconstruction plates. Plates are made of commercially pure titanium and screws are made of titanium alloy.

EQUIVALENCE TO MARKETED DEVICE

NEOORTHO Produtos Ortopédicos S/A demonstrated that, for the purposes of FDA's regulation of medical devices, Mini and Micro Fragments Reconstruction System – NEOFACE is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Synthes (USA) Craniofacial Plate and Screw System cleared under K050608,

Synthes Orbital Plates cleared under K080331,

Synthes MatrixORTHOGNATHIC Plating System cleared under K083388,

Synthes MatrixMANDIBLE Preformed Reconstruction Plates cleared under K091144,

Biomet Mandibular Fracture / Reconstruction Devices (TraumaOne) cleared under K081067,

Walter Lorenz Surgical Mandibular Fracture / Reconstruction Devices and Pre-bent Plates cleared under K063052, and

Lorenz Sterile Bone Plates and Bone Screws cleared under K972322.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium or titanium alloys. The subject and predicate plates encompass the same range of physical dimensions, including length, thickness and shape. The subject and predicate plate designs include a variety of straight and geometric configurations that are commonly used in maxillofacial trauma and reconstructive surgery, in both locking and non-locking designs. The subject and predicate screws encompass the same range of physical dimensions and include locking, non-locking, self-tapping, and self-drilling designs. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods.

Mechanical testing was performed to determine plate bending strength according to ASTM F382. Screw torsional strength, breaking angle, and axial pullout strength were determined according to ASTM F543.

Overall, Mini and Micro Fragments Reconstruction System – NEOFACE has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NEOORTHO Produtos Ortopedicos S/A
C/O Ms. Linda K. Schulz
Paxmed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

DEC 20 2010

Re: K102641
Trade/Device Name: Mini and Micro Fragments Reconstruction System – NEOFACE
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: October 19, 2010
Received: October 20, 2010

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 20 2010

510(k) Number: K102641

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Indications for Use:

Mini and Micro Fragments Reconstruction System – NEOFACE is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102641